UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TED DAVISON, WILLIAM GOULD, AND RAY LENCI, Individually And On Behalf of All Others Similarly Situated, Plaintiffs, vs. VENTRUS BIOSCIENCES, INC., DR. RUSSELL H. ELLISON, and DAVID J. BARRETT, Defendants.	)	Case: 13-cv-3119-RMB

MEMORANDUM OF LAW IN OPPOSITION OF DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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I. INTRODUCTION

The Complaint plausibly alleges that Ventrus Biosciences, Inc. ("Ventrus" or the "Company") misleadingly employed a bait and switch tactic during its Initial Public Offerings ("IPO") – using the trial drug VEN 309 as the bait – to provide Ventrus a much needed infusion of cash to stay afloat and to finance the development of VEN 307 and VEN 308, which were not far enough along developmentally to adequately raise investor interest on their own. ¶¶9, 21.[1] The detailed, well-pleaded allegations are corroborative and supported by three confidential witnesses ("CWs"), including CW1, the former Chief Medical Officer of Ventrus. The Complaint adequately alleges CW1 worked directly alongside of Defendant Russell Ellison and Vice President of Clinical Operations Dr. John Dietrich while employed at Ventrus. *See, e.g.*, ¶¶3-5, 7, 8, 13-14, 76.

Tellingly, instead of focusing their attacks on the substance of the allegations made by CW1, Defendants nibble around the edges with improper factual arguments that seek to have this Court ignore controlling Supreme Court precedent, which requires the acceptance of the Complaint's well-pleaded factual allegations as true. Indeed, despite CW1's unequivocal assertion that he worked with Defendant Ellison and Dr. Dietrich while at Ventrus, Defendants argue that CW1 could not have worked with Defendant Ellison, because CW1 ended his employment before Defendant Ellison officially began acting as a consultant to Ventrus in July 2010. Def. Br. at 12. Such arguments are legally untenable at the motion to dismiss stage and must be rejected.

Moreover, Defendants' premature arguments with respect to CW1 do not end there. Defendants strain – on several occasions – to apply case law to the allegations of the Complaint, when even a cursory review of those cases reveals that they are patently inapposite. For example,

[1] All "¶__" references are to the Complaint [Doc. # 36].

Defendants cite to *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008), to argue that CW1's purported "opinions" must be disregarded because they are not facts. Def. Br. at 13. Defendants, however, conspicuously sidestep that the court in *Elan* found that a confidential source's opinions regarding a medical diagnosis had to be disregarded because the informant "was not a physician but a data entry clerk, and Plaintiffs allege no facts indicating that CS 7 was qualified to make this or any medical diagnosis." *Id*. at 217. Here, the allegations emanate from the former Chief Medical Officer of Ventrus. Even if Defendants hope to quibble over whether or not CW1 was qualified to hold this very high-level position, which Defendants selected him to fill, a motion to dismiss is not the proper stage for such an attack.

Defendants also put forth improper fact-based arguments that their misleading statements and omissions fall under the protection of the PSLRA's safe harbor (15 U.S.C. § 78u-5), which may protect certain exclusively forward-looking statements accompanied by meaningful cautionary language, but expressly does not protect omissions or statements "made in connection with an initial public offering," 15 U.S.C. § 78u-5(b)(2)(D). First, many of Defendants' statements were made in connection with an IPO, which removes them from safe harbor protection, and, second, even if the statements are considered exclusively forward-looking, Defendants fail to carry their burden of demonstrating that these statements were accompanied by meaningful cautionary language. Here, Defendants made statements such as "[w]e believe VEN 309 has the potential to be more effective than the currently available conventional hemorrhoid topical therapies…," ¶85, when there existed no factual basis to justify the statements. Furthermore, Defendants' purported warnings, like "our research and development efforts might not result in any commercially viable products," are not substantive and tell

investors nothing they do not already know, and thus cannot be protected by the meaningful cautionary language prong of the safe harbor. The safe harbor does not apply here.

For these and the other reasons discussed herein, Defendants' motion should be denied.

II. STATEMENT OF FACTS

Ventrus is a developmental stage specialty pharmaceutical company focused on the development of late-stage prescription drugs for gastrointestinal disorders, specifically hemorrhoids, anal fissures and fecal incontinence. ¶6. The Company did not begin its operations until April 2007 when it acquired the licenses to VEN 307 and 308 with a loan from Lindsay A. Rosenwald ("Rosenwald"). ¶6. In March of the following year, with an additional loan from Rosenwald, Ventrus acquired the license to VEN 309. ¶6.

According to CW1, Ventrus' former Chief Medical Officer who worked for the Company from June 2007 up until the time Ventrus acquired the license for VEN 309, he was one of only three people working for Ventrus during this time period. ¶7. At the time CW1 resigned in March 2009, he stated that Ventrus was limping along, and could not begin any drug trials because the Company did not have any money. ¶7. VEN 309 provided the perfect conduit to infuse capital into a stagnant company. ¶8. Iferanserin ointment (VEN 309) was developed by Sam Amer, Ph. D. ("Amer"). ¶8. According to Ventrus, no prescription drugs have yet been approved by the FDA that address the cause of hemorrhoids. ¶8. Because Ventrus was limping along, the Company needed investors to pay its creditors, pay its executives' salaries, hire employees, and continue as a going concern. ¶9. The market void that VEN 309 could fill was exceptionally enticing to investors. ¶9. VEN 309 had another unique characteristic that attracted investors as well. ¶9. In contrast to VEN 307 and VEN 308, Defendants conveyed to the public that VEN 309 was ready for its Phase III trial due to its "successful" Phase IIB studies conducted

in Germany; therefore, investors could not only be comforted by the drug's previous trial experience, but could also expect to see returns on their investment in a reasonable time period. ¶9. As explained by Defendant Ellison in a June 25, 2012 conference call, VEN 307 and VEN 308 were much further behind than VEN 309. ¶9. Thus, VEN 307 and VEN 308 could never have raised enough investor interest alone to finance their development. ¶9.

On December 17, 2010, Ventrus, manned by only two employees and a part-time consultant commenced its IPO by filing a Prospectus with the SEC on Form 424B4 (the "IPO Prospectus"). ¶10. The IPO raised gross proceeds of approximately $16.1 million by touting VEN 309. ¶11. Despite being described as the Company's "lead product" in the IPO Prospectus, VEN 309 had an unproven track record. ¶12. In 1998, Amer licensed an early stage of the product to Tsumura, a Japanese pharmaceutical company. ¶12. Tsumura conducted over 350 pre-clinical and six clinical studies on the drug, but ultimately discontinued its development and turned the product back over to Amer. ¶12. Amer then conducted his own testing of the drug – a double-blind, placebo controlled, multi-center confirmatory non-pivotal Phase IIB/Phase III study in Germany – that led to Amer licensing iferanserin to Novartis Pharmaceuticals in 2003. ¶12. Novartis also conducted various toxicology and metabolite studies on the drug over the next couple of years, but then, like Tsumura, abandoned its development efforts and returned the drug back to Amer. ¶12.

CW1 explained that there were not many patients in Amer's self-financed Phase IIB/Phase III study in Germany. ¶13. Only 121 patients were studied for the Germany Phase IIB tests in contrast to the 603 studied in the Phase III trials and the 1500 required by the FDA for a chronic use drug. ¶13. Furthermore, the endpoints of Amer's Phase IIB study were based on the patients' own assessments of reduction in bleeding (primary endpoint) and pain, itchiness, and

other sensations (secondary endpoints), which were far more subjective and easier to meet than the Phase III endpoints that required a complete cessation of bleeding, pain, itchiness, etc. ¶13. Thus, while CW1 stated that potential buyers "[couldn't] say it didn't work," the Phase IIB study was not reflective of the high hurdles VEN 309 would have to overcome in the Phase III trials. ¶13. In addition to touting the earlier test results, the IPO Prospectus also emphasized that the Company had submitted a Special Protocol Assessment ("SPA") with the FDA and expected to complete the SPA process by the end of the first quarter of 2011. ¶14. CW1 explained that SPAs give investors the false impression that the FDA will likely approve the drug, when, in fact, completing an SPA has nothing to do with approval of the drug, but rather that the FDA will simply accept the study as valid protocol. ¶14. CW1 also explained that the drawback to submitting the SPA was that once FDA approved the VEN 309 SPA application, Ventrus would be locked into that protocol approved by the FDA. ¶14. In the end, the SPA filed by Ventrus was simply a ploy to lure investors to their IPO by implying that the FDA would likely approve VEN 309, because on June 22, 2011, Ventrus issued a press release explaining that they had withdrawn their SPA application with the FDA and abandoned any further plan to have the FDA approve their protocol. ¶14.

Ventrus made two additional offerings to the public during the Class Period that raised, collectively with the IPO, over $70 million. ¶15. On July 14, 2011, approximately seven months after Ventrus' first offering, the Company filed another Prospectus ("Prospectus II"). ¶15. Then, on May 30, 2012 – *less than one month* before the Company announced the complete failure of VEN 309's Phase III trials – Ventrus filed a third Prospectus ("Prospectus III"). ¶15. The prospectus accompanying each offering touted Ventrus' "lead product" VEN 309 and its successful Phase IIb/Phase III trials and investors flocked to each offering. ¶15.

Each of Ventrus' three Prospectuses, as well as Defendants' other public statements and filings made throughout the Class Period, contained false statements of material facts and omitted facts necessary in order to make the statements about Ventrus and its business operations and future prospects, including *inter alia*, the efficacy of VEN 309, the purported success of the VEN 309's Phase IIB testing, and the Company's intentions to drop the drug's SPA, in light of the circumstances under which the statements were made, not misleading. ¶16. Moreover, Ventrus included incentive bonuses for Defendants Ellison and Barrett that were tied exclusively to the Company's market capitalization. ¶17.

With regard to the money raised and spent on the VEN 309 Phase III trial, Ventrus did not finance the study like a company expecting positive results from the drug. ¶18. According to CW2, in all her 15 years of experience working on clinical trials, the VEN 309 Phase III test stood out from all the others because of the way it was managed. ¶18. First, Ventrus was "cheap" when it came to the VEN 309 trials. ¶18. Ventrus would not pay its clinical sites on time, if at all, leading to many sites asking CW2 if they would even get paid at all. ¶18. Second, Ventrus refused to pay for standard incidental procedures encountered, such as the removal of polyps in patients, which was typically part of the "standard of care" owed to the patients. ¶18.

On June 25, 2012, less than one month after the completion of the Company's third offering of shares to the public, Ventrus issued a press release in which the Company announced that it would shut down the development of VEN 309. ¶19. Despite the purported universal success evidenced by Amer's Phase IIB/Phase III VEN 309 tests in Germany, the Phase III trials conducted by Ventrus' contracted research organizations ("CROs") resulted in 603 patients – every single participant in the VEN 309 Phase III trials – failing to meet the endpoints for cessation of bleeding, itching and pain assessed in the trials. ¶19. CW2 stated that she had also

never experienced a clinical trial being cancelled in the manner that VEN 309 was shut down. ¶20. Within minutes of learning of the announced failure, she received calls from the testing sites and an email from Ventrus shutting down the whole operation. ¶20. CW2 said that ordinarily the trials take up to two years to complete because they also entail treatment, follow-up, and monitoring of patients. ¶20. Also, CW2 had been contracted for 2 studies of the drug, but Ventrus shut the trials down after the first trial. ¶20.

On June 25, 2012, when Ventrus issued a press release announcing that it would completely halt the development of VEN 309, Ventrus shares plummeted from $12.26 on the previous trading day to just $5.02, a devastating 59% decrease in Ventrus' stock value on unusually high trading volume. ¶22.

III. ARGUMENT

A. Applicable Pleading Standards

To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, a plaintiff must allege that the defendant, in connection with the purchase or sale of a security, made a false statement or an omission of a material fact, with scienter, and that reliance on defendant's action proximately caused injury to the plaintiff. *See ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009). "Any complaint alleging securities fraud must satisfy the heightened pleading requirements of the PSLRA [with respect to scienter] and Fed.R.Civ.P. 9(b) by stating with particularity the circumstances constituting fraud." *Id*. at 196 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 319 (2007)).

When analyzing a complaint for failure to state a claim pursuant to Fed.R.Civ.P. 12(b)(6), the Court must accept "all well-pleaded, non-conclusory allegations in the complaint as true and draw[] all reasonable inferences in plaintiffs' favor." *New Orleans Emples. Ret. Sys. v. Celestica,*

Inc., 455 Fed. Appx. 10, 12 (2d Cir. 2011) (summary order). "Moreover, the existence of other, competing inferences does not prevent the plaintiff's desired inference from qualifying as reasonable unless at least one of those competing inference rises to the level of an 'obvious alternative explanation.'" *New Jersey Carpenters Health Fund v. Royal Bank of Scotland Group, PLC*, 709 F.3d 109, 121 (2d Cir. 2013). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

Under the PSLRA, plaintiffs alleging securities fraud must also allege a strong inference of scienter *Celestica*, 455 Fed. Appx. at 12-13 (citing *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009)). A "strong inference" of scienter is one that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs*, 551 U.S. at 314. The scienter requirement can be satisfied here by alleging facts constituting strong circumstantial evidence of: (1) a motive and opportunity to commit fraud; or (2) knowing falsity or recklessness. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 74 (2d Cir. 2001) (citing *Novak v. Kasaks*, 216 F.3d 300, 311 (2d Cir. 2000)).

B. The Complaint Adequately Alleges Scienter

1. Plaintiffs' Confidential Witnesses Support a Strong Inference of Conscious Misbehavior or Recklessness

CW1, the former Chief Medical Officer of Ventrus, explicitly alleges that he worked directly with Defendant Ellison and Vice President of Clinical Operations Dr. John Dietrich while employed at Ventrus. ¶3. Nevertheless, Defendants urge this Court to cast aside binding Supreme Court precedent, which mandates that courts must accept well-pleaded factual allegations as true, *see Iqbal*, 556 U.S. at 679, by claiming that CW1 could not have worked with Defendant Ellison, because CW1 ended his employment before Defendant Ellison officially began acting as a consultant to Ventrus in July 2010. Def. Br. at 12. The Complaint's alleged

facts must control at this stage. *See Iqbal*, 556 U.S. at 679. Moreover, a full review of the IPO Prospectus reveals that Defendant Ellison actually worked with Ventrus "prior to his engagement in July 2010." *See* IPO Prospectus attached to Miller Decl. as Exh. A.

When viewed holistically, the Complaint's CWs directly support the theory that the Company misleadingly employed a bait and switch tactic – using VEN 309 as the bait – to provide Ventrus a much needed infusion of cash to stay afloat and to finance the development of VEN 307 and VEN 308, which were not far enough along developmentally to adequately raise investor interest on their own. ¶¶9, 21. Indeed, CW2 directly supported this theory, when she stated that Ventrus did not finance the VEN 309 Phase III trial study like a company expecting positive results from the drug. ¶18. According to CW2, in all her 15 years of experience working on clinical trials, the VEN 309 Phase III test stood out from all the others because of the way it was managed. ¶18. Specifically, despite all the capital raised in the IPOs by touting VEN 309, Ventrus was "cheap" when it came to the VEN 309 trials. ¶18. Ventrus would not pay its clinical sites on time, if at all, leading to many sites asking CW2 if they would even get paid at all. ¶18. Ventrus also refused to pay for standard incidental procedures encountered. ¶18.

Moreover, CW1, who was one of Ventrus' three employees (the other two being Defendant Ellison and Dr. Dietrich) at the time, expressed concern over the small number of participants in the German Phase IIB study. ¶98.[2] Because of the small number of patients studied, the efficacy results could not be conclusive or reliable. ¶98. Tellingly, development of VEN 309 had previously been abandoned by two other pharmaceutical companies after both conducted numerous studies and tests on the drug. ¶12. Furthermore, Defendants knew or

[2] The size and manner with which Ventrus operated also raise the inference of scienter. *See Nathenson v. Zonagen Inc*., 267 F.3d 400, 424 (5th Cir. 2001) (holding that an officer's position may create an inference of scienter when the company is a small, one product company, and the misstatements concern an important aspect of the business).

recklessly disregarded that the endpoints of Amer's Phase IIB trials were based on the patients' own assessments of reduction in bleeding (primary endpoint) and pain, itchiness, and other sensations (secondary endpoints), and therefore far more subjective and easier to meet than the Phase III endpoints that required a complete cessation of bleeding, pain, itchiness, etc. ¶99. Indeed, Defendants, and particularly Defendant Ellison, discussed the relationship between the Phase IIB and Phase III endpoints in the various prospectuses and during conference calls with analysts, but never informed investors of this important discrepancy. ¶99. Thus, Defendant Ellison knew, or at the very least should have known, the Phase IIB results were not statistically significant to the goal of meeting Phase III endpoints. ¶99.

On June 25, 2012, less than one month after the completion of the Company's third offering of shares to the public, Ventrus issued a press release announcing that the Company would completely shut down the development of VEN 309. ¶19. Not surprisingly, as this was the alleged plan all along, the Company explained that "it believe[d] that current resources would be better allocated toward the planned completion of its VEN 307 … and the beginning of further development of VEN 308…" ¶91. CW2 stated that in 15 years she had never experienced a clinical trial being cancelled in the manner that VEN 309 was shut down. ¶20. Within minutes of learning of the shutdown, CW2 received calls from the testing sites and an email from Ventrus shutting down the whole operation. ¶20. CW2 said that ordinarily the trials take up to two years to complete because they also entail treatment, follow-up and monitoring of patients. ¶20. Also, CW2 had been contracted for 2 studies of the drug, but Ventrus shut the trials down after the first trial. ¶20. Despite the purported universal success evidenced by Amer's Phase IIB/Phase III VEN 309 tests in Germany, the Phase III trials conducted by Ventrus' contracted CROs resulted

in 603 patients – every single participant in the VEN 309 Phase III trials – failing to meet the endpoints for cessation of bleeding, itching and pain assessed in the trials. ¶19.

Therefore, Plaintiffs' reliance on three CWs, including the former Chief Medical Officer of Ventrus, adequately provides a basis for finding strong circumstantial evidence of conscious misbehavior or recklessness as to each Defendant. *See In re Scholastic Corp. Sec. Litig.*, 252 F.3d at 74; *see also* ¶¶3-5.

Nevertheless, Defendants claim that this Court, relying on *Higginbotham v. Baxter Int'l Inc.*, 495 F.3d 753, 757– 58 (7th Cir. 2007), held that CW allegations must always be discounted. Def. Br. at 12. The Second Circuit, however, has repeatedly approved the use of confidential witnesses where, as here, plaintiffs describe the source in the complaint "with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Novak*, 216 F.3d at 314; *see also Celestica*, 455 Fed. Appx. at 13 (applying the *Novak* standard to evaluate CWs); *New Jersey Carpenters Health Fund*, 709 F.3d at 123-24 (same). Further, *Higginbotham* was subsequently, severely limited by that same court in *Makor v. Tellabs,* 513 F.3d 702 (7th Cir. 2008). *See id.* at 712 (on remand from the Supreme Court in *Tellabs*, distinguishing *Higginbotham* as limited to its narrow facts and holding that "the absence of proper names does not invalidate the drawing of a strong inference from [the confidential witnesses'] assertions").

Defendants also cite to *Campo v. Sears Holdings Corp*., 371 Fed. Appx. 212, 216 n.4 (2d Cir. 2010) to assert the same erroneous conclusion that CWs must be discounted. Def. Br. at 12. The Second Circuit in *Campo*, however, did not adopt a blanket rule calling for the discounting of CW allegations regardless of circumstance. 371 Fed. Appx. at 216. To the contrary, the court analyzed all of the sources' allegations as a whole, as mandated by *Tellabs*, and simply found

they failed to give rise to a strong inference of scienter, because, *inter alia*, their allegations were "general and unsupported." *Campo,* 371 Fed. Appx. at 335. More importantly, the Second Circuit in *Campo* was faced with the unique situation where the district court allowed the complaint's CWs to be deposed prior to a ruling on the motion to dismiss, and, at one of the depositions, a CW "expressly disclaimed [an] allegation, attributed to him in the complaint…" *Id*. at 216. Thus, the facts from *Campo* are easily distinguishable.

Here, the Complaint particularly describes in great detail each CW, his/her position, when he/she was employed, and how he/she obtained the information that he/she alleges. *See*, *e.g.*, ¶¶3-5, 7-22. For example, CW1 is described as the former Chief Medical Officer of Ventrus who worked for the Company in this capacity from June 2007 to March 2009, and it is explicitly alleged that he worked directly with Defendant Ellison and Vice President of Clinical Operations Dr. John Dietrich. ¶3. The Complaint alleges that CW2 is a Clinical Research Associate with LCH Clinical Research LLC since June 2005, and worked on the Phase III trial of VEN 309 under a contract with Armonia Clinical Research, a CRO run by Christina DiArchangelo Puller, an employee of Ventrus, and has fifteen years of experience working on clinical trials. ¶4. Accordingly, each CW readily satisfies the *Novak* standard, and should not be discounted under *Novak* and its progeny.

Next, Defendants assert that CW1 and CW2's allegations are irrelevant because they fail to allege either spoke directly to Defendants, *see* Def. Br. at 12-13, but this contention directly conflicts with the mandates of *Tellabs* and *Slayton*. *See Tellabs*, 551 U.S. at 323; *Slayton v. Am. Express Co.*, 604 F.3d 758, 775 (2d Cir. 2010). In fact, the Second Circuit in *Slayton* stated: "We rest our conclusion 'not on the presence or absence of certain types of allegations, but on a practical judgment about whether, accepting the whole factual picture painted by the Complaint,

it is at least as likely as not that defendants acted with scienter.'" *Id*. (quoting *Inst. Investors Group v. Avaya, Inc.*, 564 F.3d 242, 269 (3d Cir. 2009)).[3] Accordingly, Defendants' argument that the absence of a certain type of allegation – such as a particular conversation with Defendants – can render the Complaint's scienter allegations inadequate, is inescapably flawed.[4]

Furthermore, Defendants wrongly claim that any purported opinions from CW1 should be disregarded here, because "Plaintiffs must rely on facts, not opinions or conclusions, when utilizing CWs." Def. Br. at 13 (citing *In re Elan Corp. Sec. Litig*., 543 F. Supp. 2d 187, 217 (S.D.N.Y. 2008)). As discussed above, this case holds no such thing because the facts in *Elan* are a far cry from here, where any purported opinions attributed to CW1 are not the opinions or conclusions of a data entry clerk but the Chief Medical Officer of the Company – a person certainly qualified to state facts or express opinions regarding the Company's drug trials. ¶3.

Finally, the Complaint also establishes a strong basis for the use of the "core operations" inference. *See* ¶¶104-06. The "core operations" inference allows courts to impute knowledge of facts to "key officers" relating to the "core operations" of their company. *See Bd. of Trs. of Ft. Lauderdale Gen. Emples. Ret. Sys. v. Mechel OAO*, 811 F. Supp. 2d 853, 871 (S.D.N.Y. 2011); *see also In re Forest Labs. Sec. Litig*., No. 05 Civ. 2827, 2006 U.S. Dist. LEXIS 97475, at *32 (S.D.N.Y. July 19, 2006) (Berman, J.). Here, Ventrus acknowledged VEN 309 to be its "lead

[3] Notably, the Third Circuit in *Avaya* expressly rejected an argument similar to the one made here by Defendants: "The existence of such a direct link [such as a "particular document or conversation"] would fortify Shareholders' allegations that defendants' statements about discounting were knowingly or recklessly false. But the Supreme Court has made clear that plaintiffs' allegations of scienter 'need not be irrefutable, *i.e.*, of the 'smoking-gun' genre.' *Tellabs*, 127 S. Ct. at 2510." *Avaya*, 564 F.3d at 268-69.

[4] Defendants also rely on one out of circuit district court case to claim "allegations relating to events that took place after he left Ventrus must be disregarded." Def. Br. at 12 n.10. The argument, however, holds no weight, as the Second Circuit has repeatedly held that both post-class-period data and pre-class data can be used to "confirm what a defendant should have known during the class period." *In re Scholastic Corp. Sec. Litig*., 252 F.3d at 72 (citing *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000) and *Novak*, 216 F.3d at 312-13).

product." As Ventrus' "lead product" during the Class Period, VEN 309 and its FDA approval were of critical importance to the Company. ¶104. Given that Ventrus' entire business hinged on the development of these three drugs – VEN 307, VEN 308 and VEN 309 – and that VEN 309, as their acknowledged "lead product," was the furthest developed and most marketable of the three drugs, Defendants knew or should have known of VEN 309's ineffectiveness and that the Company had overstated the success of Phase I and Phase II. ¶104. Furthermore, Defendants Ellison and Barrett were the highest-level or key officers and directors of Ventrus during the Class Period. ¶105. Therefore, by virtue of their high-level positions and the integral role VEN 309 played in the Company's survival as a going concern, Defendants Ellison and Barrett knew or should have known the adverse facts regarding, *inter alia*, VEN 309's efficacy that contradicted their public statements. ¶106.[5]

2. Defendants' Attack on Plaintiffs' Motive Allegations Fail

Defendants focus the brunt of their attack on what the Complaint does not allege as motive, instead of what the Complaint does allege. Def. Br. at 10. Even though motive allegations are not required under *Tellabs*, the Complaint alleges significant concrete benefits realized by Defendants Ellison and Barrett resulting from their misleading statements or nondisclosures. *See Tellabs*, 551 U.S. at 325 ("the absence of a motive allegation is not fatal");

[5] Defendants seem to imply that the "core operations" inference is no longer viable after the passage of the PSLRA. *See* Def. Br. at 16 ("this Court has carefully considered the continued viability of the 'core operations' inference in light of the PSLRA's heightened pleading requirement and found it lacking." (quoting *Shemian v. Research in Motion Ltd.*, 2013 WL 1285779, at *18 (S.D.N.Y. Mar. 29, 2013))). Defendants, however, leave out two critical sentences from *Shemian* following the foregoing statement: *Shemian* actually held that the "core operations" inference is not "independently sufficient to raise a strong inference of scienter," but that the inference must still be considered "as part of [a court's] holistic assessment of the scienter allegations." *Id*. Thus, the case does not support the argument that "core operations" inference is no longer viable on any level. Indeed, numerous courts in this district – including this one – have cited to "core operations" inference with approval. *See Mechel OAO*, 811 F. Supp. 2d at 872 (gathering cases); *see also In re Forest Labs. Sec. Litig.*, 2006 U.S. Dist. LEXIS 97475, at *32.

see also ¶100. As a preliminary matter, Ventrus could not afford to develop and test VEN 307 and VEN 308 without investor support, and VEN 307 and 308 were not far enough along in their development to garner such financial support. ¶¶100-02. As a result, the Company was motivated to exaggerate the Phase IIB results of VEN 309 in order to finance the development of VEN 307 and VEN 308 and continue Ventrus as a going concern. ¶100.

Moreover, the Complaint further alleges that Defendants Ellison and Barrett were also motivated to mislead investors regarding the success of the Phase IIB study, the efficacy of VEN 309 and the planned use of IPO and subsequent offering proceeds because Ellison and Barrett personally profited from Defendants' misrepresentations. ¶101. First and foremost, Ellison and Barrett would receive bonuses directly tied to the market capitalization of Ventrus. ¶101. Specifically, Ellison and Barrett would receive a bonus of $250,000 if Ventrus' market capitalization exceeded $100 million. ¶101. Ventrus achieved this milestone in August 2011, and Ellison and Barrett received their bonuses shortly thereafter. ¶101. Ellison and Barrett would also receive a bonus of $500,000 if the Company's market cap exceeded $250 million. ¶101. Thus, the more money Ellison and Barrett raised in public offerings and the more investors were misled to believe VEN 309 would receive FDA approval, the more money Ellison and Barrett would receive in bonuses. ¶101.[6]

[6] Defendants also shamelessly argue that Plaintiffs' scienter allegations as to Defendants Ellison and Barrett are undermined because they increased their personal holdings by 103% during the Class Period (Def. Br. at 10), knowing fully well that the increase in holdings was substantially related to equity awarded by the Company as an incentive. *See* Exh. B attached to Miller Decl. Even where there are actual purchases of stock during the class period, such facts do not necessarily defeat motive allegations. *See In re Cardinal Health Inc. Sec. Litig*., 426 F.Supp.2d 688, 731 (S.D. Ohio 2006) ("This Court is persuaded, however, that 'the calculus is clearly more calculated [because] 'an insider may not always trade all his shares in the company for which he possesses the inside information; the trader may hold on to a portion of his shares to hedge against the unforeseen or to obscure the insider trading from the SEC.'") (quoting *In re Worlds of Wonder Sec. Litig*., 35 F.3d 1407, 1427 (9th Cir. 1994).

C. Defendants' Fact-Based Arguments are Premature and Must Fail

1. Defendants' Misstatements or Omissions of Material Fact

The Complaint adequately alleges that Defendants made materially false and misleading statements and omissions that concealed true, adverse facts about, *inter alia*, the use of IPO proceeds for VEN 309, the efficacy of VEN 309, and its likelihood of FDA approval. *See* ¶¶32-88. Nonetheless, Defendants attempt to redirect the Court's focus away from the actual falsity of their statements by quibbling about the Complaint's use of block quotes, claiming that this approach "does not tether the specific false statements to the specific reasons why each statements was false when made." Def. Br. at 16-17 (citing *Tabor v. Bodisen Biotech, Inc*., 579 F. Supp. 2d 438, 452-53 (S.D.N.Y 2008)). This argument is nothing more than a red herring.

In *Tabor*, the court found that plaintiffs' use of "large block quotes … followed by generalized explanations of how the statements were false or misleading [was] not sufficient to satisfy the heightened pleading requirements." *Id*. at 453. A review of the *Tabor* complaint, *see* Exh. C attached to Miller Decl., reveals that plaintiffs in that case quoted large block passages of SEC filings in multiple sequential paragraphs, *see* Exh. C at ¶¶35-43, and then concluded the entire sequence with one paragraph using bullet points to generally allege the falsity of all the preceding paragraphs, *see* Exh. C at ¶44. Thus, the format used by plaintiffs in *Tabor* was not adequate because it did not specify how *each* statement was false or misleading when made.

Contrary to *Tabor*, each statement alleged to be false or misleading here is immediately followed in the next paragraph by the reasons – with supporting facts – why that statement was false or misleading when made, *see, e.g.*, ¶¶63-64, 69-70, 71-72, the Complaint identifies the speaker of the statements, *see, e.g.*, ¶¶46, 48, 50, and states when and where the statements were made, *see*, *e.g.*, ¶¶48, 50, 55. Rule 9(b) requires nothing more. *See Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004) ("[Plaintiffs' must] (1) specify the statements that the plaintiff contends

were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent."). Therefore, the *Tabor* case has no application here, and Defendants argument is without merit.

a. Statements Regarding the Use of IPO Proceeds

Plaintiffs have adequately alleged that Defendants made false and misleading statements regarding Ventrus' planned use of IPO proceeds for VEN 309. *See, e.g.*, ¶¶46-47, 69-70. Defendants stated in their IPO Prospectus that they intended to "use the proceeds from this financing to contract with clinical research organizations, or CROs, to conduct the first of the two required Phase III clinical trials with VEN 309…" ¶46. Although partially true, because Ventrus did use some of the proceeds to conduct a clinical trial for VEN 309, the Complaint plausibly alleges that this statement was still false or misleading when made because Defendants failed to disclose that the proceeds from the IPO were not primarily intended for VEN 309 testing. *See United States SEC v. Syron*, 934 F. Supp. 2d 609, 629 (S.D.N.Y. 2013) ("The law is well settled . . . that so called 'half truths' — literally true statements that create a materially misleading impression — will support claims for securities fraud."); *see also* ¶47. Rather, the primary purpose of the IPO was to repay the Company's creditors, pay Defendants Ellison and Barrett's bonuses tied to market cap, finance the development of VEN 307 and 308, and continue Ventrus as a going concern. ¶¶9, 47. Indeed, CW2 alleged that Ventrus did not finance the VEN 309 study like a company expecting positive results from the drug. ¶18. Further, when the Phase III trials conducted by Ventrus' contracted CROs resulted in 603 patients – ***every single participant*** in the VEN 309 Phase III trials – failing to meet the endpoints for cessation of bleeding, itching and pain assessed in the trials, Ventrus immediately terminated the development of VEN 309, according to CW2. ¶¶19-20. Of course, the Complaint alleges that one

of the reasons the termination of VEN 309 was so abrupt, was to preserve scarce resources for the true intended targets of the IPO financing – VEN 307 and VEN 308. ¶91.

b. Statements Regarding the Phase III Study Progress

Defendants contend that Plaintiffs' inappropriately use "20-20 hindsight" to argue that their statements regarding the positive progress of the Phase III study were false or misleading when made because the trial ultimately did not meet its endpoints. Def. Br. at 20. The Complaint, however, does not contend that Ventrus made statements that were incorrect because they ultimately proved to be inaccurate in light of subsequent events; rather, Plaintiffs allege that Defendants had access to information that undermined the Company's statements at the time they were issued. *See*, *e.g.*, ¶¶72, 76, 78; ¶74 ("The foregoing statements were materially false and/or misleading when made because Defendants knew or recklessly disregarded that this [progress] data was based upon a study that, according to CW1, Ventrus' former chief medical officer, used too few patients glean the true efficacy of the drug.").

Next, Defendants state that the Complaint "wrongly attributes fraud to Dr. Ellison's statement in November 2011 that 'no serious severe adverse events related to the drug have been seen to date.'" Def. Br. at 20 (quoting ¶68). The Complaint plausibly alleges that this statement was false or misleading when made because "the drug's total ineffectiveness was a severely adverse event relating to the drug's chances of FDA approval." ¶68. Defendants, however, argue that the Complaint's allegations of falsity are twisting the reading of Defendant Ellison's statement because the term "severe adverse events" is a "well-known industry term referring to whether the drug had caused death, injury or other toxic effects." Def. Br. at 20. The term was not defined in Defendant Ellison's statement, nor was any reference made to any industry regulation defining the term, and, thus, Defendants are improperly attempting to insert their own facts and inferences regarding the meaning of statement. But, at this stage, the Complaint's

factual allegations must be accepted as true at this stage, and all reasonable inferences must be drawn in Plaintiffs' favor. *See, e.g., Celestica*, 455 Fed. Appx. at 12. Therefore, the statement was false or misleading when made because none of the participants in the VEN 309 Phase III trial experienced the required relief from hemorrhoid symptoms to allow the trial to meet its endpoints, and this was a severely adverse event relating to the drug's chances of FDA approval. ¶68.

On November 14, 2011, Ventrus issued a press release announcing that it extended the timing to report the top line results from Phase III trial of VEN 309 by approximately three months. ¶69 ("As we expect to report top line Phase 3 results for both products in the second quarter of 2012, these milestones are likely to be close together in time...."). With respect to this statement, Defendants again attempt to improperly insert their own more favorable factual explanation for the delay. *See* Def. Br. at 21; *see also Celestica*, 455 Fed. Appx. at 12. The Complaint, however, plausibly alleges that the Company misleadingly failed to disclose to investors that the reason why Ventrus delayed reporting for Ventrus' top line Phase III results was because Ventrus planned to effectuate a third offering of stock to infuse the Company with capital prior to releasing the VEN 309 study results that Ventrus knew or should have known would be unfavorable. ¶70. In fact, on June 25, 2012, less than one month after the completion of the Company's third offering of shares to the public, Ventrus issued a press release in which the Company announced that it would shut down the development of VEN 309. ¶19.

c. Statements Regarding the Phase IIb Study Sample Size

Defendants argue that their statements regarding the unreliable sample size of the Phase IIb study was not false or misleading, because "defendants repeatedly disclosed the 121-patient size of the Phase IIb trial." Def. Br. at 18. The argument misses its mark, as Plaintiffs admittedly

do not contest whether Defendants accurately disclosed the sample size of the Phase IIb trial, but rather Defendants' failure to disclose the inconclusiveness and unreliability of the results generated from this particular Phase IIb trial – in part due to the small sample size. *See, e.g.*, ¶¶37, 39, 54, 58. Further, contrary to Defendants' authority holding that the securities laws do not recognize a fraud premised on a *plaintiff's* criticisms of a drug trial's methodology, *see* Def. Br. at 18, the Complaint here alleges that Ventrus' own Chief Medical Officer was the one criticizing the ability of using the results gleaned from Phase IIb to accurately determine the true efficacy of VEN 309, yet this materially adverse information remained undisclosed. ¶76. Indeed, Defendants' authority only holds that "'[d]efendants are not required to adopt [plaintiff's] view' as to whether the results were aberrational." *Abely v. Aeterna Zentaris Inc.*, No. 12 Civ. 4711, 2013 U.S. Dist. LEXIS 78388, at *28 (S.D.N.Y. May 29, 2013) (quoting *Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013)).

d. Statements Regarding an SPA for the Phase III Study

Defendants raise two untenable arguments regarding the alleged falsity of their statements concerning the SPA. *See* Def. Br. at 18-19. Both arguments are premised on the fact that the Complaint "points to no document, record or conversation to indicate" that: 1) "at the time Ventrus announced that it was pursuing an SPA, it did not have a genuine intent to obtain one," and 2) that "Dr. Ellison's statements characterizing discussions with the FDA as 'productive' were false when made." Def. Br. at 19. Plaintiffs are not required to point to a specific "document, record or conversation;" rather they need only plead facts sufficient to support Plaintiffs' belief that the statements were false when made. *Rombach*, 355 F.3d at 172.

In its IPO Prospectus filed on December 17, 2010, Ventrus stated that "we expect to complete the SPA process by the end of the first quarter of 2011." ¶44. The Complaint alleges this statement was false or misleading when made because Ventrus did not, in fact, expect to

complete the SPA process by the end of the first quarter of 2011. ¶45. Instead, Defendants merely used the SPA to lure investors to the IPO, because, according to CW1, investors would misinterpret the SPA as an indication that the FDA would approve VEN 309. ¶¶45, 60. Indeed, by July 2011, Defendants abandoned its SPA application. ¶¶45, 60. Therefore, Defendants did not reasonably "expect to complete the SPA process by the end of the first quarter of 2011."

Next, the Complaint alleges that Defendants' statement regarding the SPA process for the first pivotal trial with VEN 309 being "productive" was false or misleading when made. ¶55. The foregoing statement, however, was materially false or misleading when made because the SPA was not, in fact, "productive" with regard to FDA approval of VEN 309, as the acceptance of the FDA's suggested definitions and endpoints only raised the bar for demonstrating the drug's efficacy, and thus made the FDA approval hurdle for the drug – the efficacy of which was entirely unproven – even higher and more unattainable. ¶¶49, 56.

2. The Safe Harbor is Inapplicable

The PSLRA safe harbor is narrow in scope, applying exclusively to statements that are forward-looking and accompanied by meaningful cautionary language. 15 U.S.C. § 78u-5(c)(1)(A)(i). Notably, the safe harbor does not apply to any statement "made in connection with an initial public offering," 15 U.S.C. § 78u-5(b)(2)(D), and "the safe harbor does not apply to material omissions," *City of Providence v. Aeropostale, Inc.*, No. 11 Civ. 7132, 2013 U.S. Dist. LEXIS 44948, at *32, 37-38 (S.D.N.Y. Mar. 25, 2013). *See* 15 USC § 78u-5(a) ("This section shall apply only to a forward-looking statement…"). The safe harbor also does not apply to statements that contain a mixture of past, present and future aspects. *See Avaya*, 564 F.3d at 255; *In re Nortel Networks Corp. Sec. Litig.*, 238 F.Supp.2d 613, 629 (S.D.N.Y 2003).

"To avail themselves of safe harbor protection under the meaningful cautionary language prong, defendants must demonstrate that their cautionary language was not boilerplate and conveyed substantive information." *Slayton*, 604 F.3d at 772. "A vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation." *Id.* (quoting *Avaya*, 564 F.3d at256). "The requirement for 'meaningful' cautions calls for 'substantive' company-specific warnings based on a realistic description of the risks applicable to the particular circumstances, not merely a boilerplate litany of generally applicable risk factors." *Slayton*, 604 F.3d at 772 (quoting *Southland Sec. Corp. v. INSpire Ins. Solutions Inc.*, 365 F.3d 353, 372 (5th Cir. 2004)).

Here, Defendants point to only two misleading statements alleged in the Complaint, and then assert a blanket proclamation that all of "Defendants' statements about VEN 309 and the drug's prospects for FDA approval were inherently forward-looking and fall squarely under the safe harbor." Def. Br. at 23 (citing ¶¶63, 87). First, many of the statements in the Complaint – including ¶87 – were "made in connection with an initial public offering," and thus are not protected by the safe harbor. 15 U.S.C. § 78u-5(b)(2)(D). Second, contrary to their blanket assertion, many of Defendants' statements are just plainly not forward-looking. *See, e.g.*, ¶67 ("[N]o serious severe adverse events related to the drug have been seen to date.").

Moreover, "statements of reasons, opinion, or belief," even about a "drug's prospects for FDA approval," Def. Br. at 23, may be actionable under the securities laws where they "are reasonably understood to rest on a factual basis that justifies them as accurate, the absence of which renders them misleading." *Desai v. General Growth Properties, Inc.*, 654 F.Supp.2d 836, 855 (N.D. Ill. 2009) (citing *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1093 (1991)). Indeed, in *Desai*, the court found language such as "[General Growth] currently anticipate[s] that

we will be able to repay or refinance all of our debt on a timely basis" was not forward-looking because it was framed in the then present and was a verifiable fact. 654 F.Supp.2d at 852. "Other statements, such as 'We believe the approval of Replagal [drug] in the U.S. remains a when not if proposition'… arguably do not fall within the safe harbor provisions. They are statements of present belief that are material… It is inappropriate to dispose of such statements on a motion to dismiss." *In re Transkaryotic Therapies, Inc. Secs. Litig.,* 319 F.Supp.2d 152, 162 (D. Mass. 2004).

Similarly, here, Defendants made statements such as "we intend to initiate and conduct the second Phase III trial…" ¶83. These statements are framed in the then present, are verifiable fact, and therefore are unprotected under the PSLRA. Additionally, reasonable investors would believe that there would be some factual basis to justify the foregoing statements; however, there existed no such basis. The Complaint alleges that the data relied upon by Ventrus was woefully inconclusive and unreliable due to the small sample sizes used in Amer's studies, *see* ¶86, that Defendants omitted that they never truly intended to conduct a second Phase III trial, because Defendants were attempting to draw investors to their third offering before the inevitable publication of the devastating Phase III results, *see* ¶84. Therefore, these statements were materially misleading and were of present belief, and thus, these statements, *inter alia*, cannot be considered forward-looking under the PSLRA safe harbor.

Next, Defendants contend that all of their statements were accompanied by meaningful cautionary language. *See* Def. Br. at 23-25 (quoting Exh. T of Def. Br.) (Ventrus may not "receive regulatory approvals;" "our research and development efforts might not result in any commercially viable products;" and "[t]he failure of clinical trials . . . could cause us to abandon a product candidate"). These purported warnings tell investors nothing of substance and nothing

they do not already know, and thus are not meaningful. *See In re Amylin Pharms., Inc. Secs. Litig.*, No. 01cv1455, 2002 U.S. Dist. LEXIS 19481, at *26-27 (S.D. Cal. Oct. 9, 2002) ("[M]erely warning investors that FDA may not approve the drug tells them something they already know."); *see also Irvine v. ImClone Sys.*, No. 02 Civ. 109, 2003 U.S. Dist. LEXIS 9342, at *3-4 (S.D.N.Y. June 3, 2003); *In re Sepracor, Inc. Sec. Litig.*, 308 F. Supp. 2d 20, 34 (D. Mass. 2004). Further, the purported warnings singled out by Defendants are so boilerplate that they could be applied to practically *any* issuer attempting to gain approval of *any* drug from the FDA. *See, e.g., Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110, 1123 (C.D. Cal. 2005) (finding purported warnings such as "acceptance of new products [by consumers]" and "approval is never certain" are not meaningful, because they are "so broad that they apply to *any* business that sells products to consumers" and can apply to "literally any issuer subject to FDA regulation."); *see also Slayton*, at 604 F.3d at 773.

The Complaint also alleges that Ventrus issued these boilerplate litany of generally applicable risk factors regarding the potential success and FDA approval of VEN 309 when, at the time of issuing these purported warnings, information and facts were present that would seriously undermine many of Ventrus' statements. *See, e.g.*, ¶21. Although the issue has not been definitively decided, the Second Circuit in *Slayton* noted that defendants are likely not protected by the meaningful cautionary language prong of the safe harbor where their cautionary statement omitted a major risk that they faced at the time the statements were made. *Slayton*, 604 F.3d at 772 n.8 (citing *Asher v. Baxter International Inc.*, 377 F.3d 727, 734 (7th Cir. 2004)). As no meaningful cautionary language accompanied Defendants' statements, they cannot be immunized under the safe harbor.

3. Defendants' Statements Are Not Inactionable Puffery

Defendants contend that some of their statements are inactionable, because they use "words like 'encouraging' [which] are the type of 'expressions of puffery and corporate optimism' that do not generally 'give rise to securities violations.'" Def. Br. at 21. At this stage, in order to dismiss on this highly factual ground, "the court must be convinced that the market could 'easily' determine the statements at issue to be nothing more than immaterial puffery." *In re Sprint Corp. Sec. Litig.*, 232 F.Supp.2d 1193, 1219 (D. Kan. 2002). Statements of corporate optimism are now viewed with disfavor and the "recent trend is to consider expressions of corporate optimism carefully." *See Brumbaugh v. Wave Systems Corp.*, 416 F. Supp. 2d 239, 250 n.11 (D. Mass. 2006). Here, for example, the Complaint states that despite representing that "we believe that [the commercial potential of VEN 309] could considerably enhance the value of the asset to the Company," *see* Def. Br. at 22, Defendants omitted to disclose, *inter alia*, that VEN 309 was never on a track to development and manufacture, *see* ¶21, and that the Company was motivated to exaggerate the Phase IIB results of VEN 309 in order to finance the development of VEN 307 and VEN 308 and continue Ventrus as a going concern, *see* ¶100. Therefore, at this stage, Defendants' statements cannot be dismissed as immaterial corporate optimism.

D. The Complaint Adequately Pleads Control Person Liability

Contrary to Defendants' assertion, *see* Def. Br. at 25, Plaintiffs have adequately pleaded the underlying § 10(b) claims with legal sufficiency, and thus, secondary liability under § 20(a) is also adequately pleaded.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss should be denied in its entirety.

Dated: December 23, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2013, I filed Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Class Action Complaint upon all counsel of record by using the CM/ECF system and via e-mail. The CM/ECF system will provide service of such filing(s) via Notice of Electronic Filing (NEF).

s/ Kim E. Miller
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